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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,926

02/06/2004

Ted H. Pacha

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3709

MAIL DATE

DELIVERY MODE

08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/773,926

Applicant(s)

PACHA ET AL.

Examiner

Shefali D. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/06/2004
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/06/2004, 08/11/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method of immunization identification, classified in class 604, subclass 500.
 - II. Claims 11-15, drawn to an immunization identification system, classified in class 40, subclass 638.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product, such as, applying the color-coded strips of the immunization identification system on to different binders or notebooks that belong to the same category.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Kirk Hartung on 7/20/07, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation

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of this election must be made by applicant in replying to this Office action. Claims 11-15 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
7. The following title is suggested: A Universal Method of Immunization Identification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (US 2004/0158186) in view of Walsh (US 6,464,136).

In regards to claim 1, Hall describes an adhesive bandage that can be used for the identification of a vaccine administered at an injection site. In Hall (page 2, claim 11), a method of vaccination is described comprising the administration of a vaccine by injection into a recipient at a vaccination site and the application of adhesive bandage to the vaccination site. The exposed surface of the bandage displays indicia that identify the vaccine that was administered. While not explicitly stated by Hall, a syringe must be intrinsically filled with an immunization dosage in order to administer a vaccine. Hall does not teach the application of a colored adhesive-backed strip to a syringe and the application of another colored adhesive-backed strip to a medical chart of a patient. However, Walsh further describes a method for the verification of the identity of a patient undergoing medical treatment. In the claims of Walsh (column 33, lines 61-67 to column 34, lines 1-11), a method for the identification of a patient and their treatments is described comprising the use of a syringe and the application of labels to drug containers, syringes, and to at least one "patient identification member." The "patient identification member" can be a patient treatment chart. In the specification of Walsh (column 28, lines 32-34), the syringe is filled with an appropriate drug and a label is placed on the syringe. Concerning the "patient identification member" of Walsh (column 34, lines 7-11), it can be a "patient treatment chart," which according to a person having ordinary skill in the art, is synonymous to the "medical office chart of the patient." In the specification of Walsh (column 28, lines 23-27), printed on the label is the name of the patient and a barcode that references treatments. It would have been obvious to a person having ordinary skill in the art to incorporate the teachings of Walsh to the teachings of

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Hall because doing so would further facilitate in the verification of a patient who is undergoing medical treatments, such as the administration of immunizations, and avoid unnecessary medical error.

In regards to claim 2, which is dependent on claim 1, it describes the same method of immunization identification as claim 1 but is used for a second immunization dosage. Hall (page 3, claim 13) suggests the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site.” To a person having ordinary skill in the art, with the teachings of Hall and Walsh, it would be obvious that the method for the administration of the first immunization dosage and application of the labels to the first immunization apparatuses is the same as the method for the administration of the second immunization dosage and application of labels to the second immunization apparatuses. These methods aid in the tracking of more than one immunization to avoid medical error.

In regards to claim 3, Hall does not teach the application of a strip to a home chart of the patient, but to a person having ordinary skill in the art, it can be inferred from the teachings of Walsh (column 34, lines 7-11) that a home chart contains the same information about the history of a patient’s medical treatments as the “patient treatment chart.” Walsh (column 33, lines 65-67) also teaches of a “plurality of identical patient identifier carrying labels” that can be applied to “a patient identifying member” such as “a patient treatment chart” (column 34, lines 7-11). It would be obvious to a person having ordinary skill in the art to apply these teachings of Walsh to those of Hall in order for a patient to have the ability to keep track of immunizations that have been administered to them through a chart and to avoid medical error.

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In regards to claim 6, Hall does not teach of a series of stickers with a common first indicia that correspond to first immunization apparatuses, but Walsh (column 33, lines 65-67) teaches that the identification labels are a “plurality of identical patient identifier carrying labels.” It would be obvious to a person having ordinary skill in the art that if the labels are identical, they have a common indicia. Furthermore, it would be obvious to apply these teachings of Walsh to those of Hall in order to set up a group of similar labels that can be applied to all of the apparatuses used in a single immunization procedure.

In regards to claim 7, which is dependent on claim 6, it requires a “common second indicia” for the second immunization. As cited above for claim 6 with Walsh (column 33, lines 65-67), it would be reasonable to expect that the second immunization would also have a set of similar identification labels in comparison to those of the first immunization. As cited above for claim 2, in Hall (page 3, claim 13), there is a suggestion for the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site.” To a person having ordinary skill in the art, with the teachings of Hall and Walsh, it would be obvious that each immunization will have its own common indicia in order to distinguish one immunization from another. This is the purpose of the immunization identification system. And again the motivation for this immunization identification method is for the tracking of more than one immunization to avoid medical error.

In regards to claim 8, “the first and second indicia are first and second colors.” Hall (page 2, claims 1-3) teaches that different forms of indicia, including color, are used to identify different vaccines.

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In regards to claim 9, Hall does not teach of the series of stickers being applied to the home chart of the patient, but Walsh (column 34, lines 7-11 and column 33, lines 65-67), as mentioned above with claim 3, teaches of a “patient treatment chart” to which corresponding labels are applied. To a person having ordinary skill in the art, the “patient treatment chart” would be synonymous to “the home chart of the patient” since they perform the same function of medication record keeping. It would be obvious to apply the teachings of Walsh to those of Hall so that a patient can apply one label of a series of labels to his own home chart in order to keep track of his own different immunizations.

10. Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall and Walsh as applied to claim 1 or claim 7 above, and further in view of West et al (US 2002/0162261).

In regards to claims 4 and 5, Hall does not teach of providing a color on the immunization vial. Walsh (column 34, lines 1-6) teaches that labels are applied to the drug containers for identification purposes. In West et al (page 4, claims 8-9), it is taught that similar color-coded identification stickers are placed on drug containers and on their caps as well. It would be obvious to apply the teachings of Walsh and West to those of Hall in order to properly identify medication containers and to avoid medical error.

In regards to claim 10, Hall does not teach of providing indicia on the immunization vials. As mentioned by Walsh, above in paragraph 10, labels are applied to the drug containers for identification purposes. And West et al, above in paragraph 10, teaches that similar color-coded identification stickers are placed on drug containers and on their caps as well. Also, as stated

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above in paragraph 9, in Hall (page 3, claim 13), there is support for the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site.” It would be obvious to apply the teachings of Walsh and West to Hall so that different immunization indicia labels are applied to different immunization vials. The motivation for this is to track the different medications, or immunizations, administered to a patient and to avoid medical error.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- i) JP 2002-132154 contains a drug management labeling system with a drug container label and a syringe label that are also relevant to the application claims.
- ii) US 2003/0055685 contains a system and method for the monitoring of the administration of medical products in which one product identifier uploads a patient's medical record to a medicine data storage device.
- iii) US 5,692,640 contains a syringe content identification system in which one label can be used to identify a syringe and later applied to a patient's permanent record to justify immunization administration.
- iv) US 2002/0017784 contains a system and method for labeling syringes containing pharmaceuticals and for monitoring the administration of pharmaceuticals.

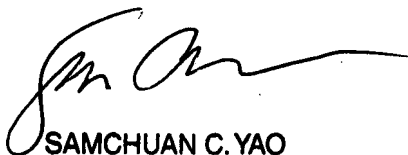
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shefali D. Patel whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDP
07/31/07


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SUPERVISORY PATENT EXAMINER